

Form PTO/SB-1449

Docket Number 554792000401

Application Number 10/674,684

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

Applicant

Allan I. Bain et al.

(Use several sheets if necessary)

Filing Date September 29, 2003

Group Art Unit 1626

Mailing Date October 28, 2004

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
RB	1.	9/27/60	2,954,380	Shapiro et al.	1	1	
RB	2.	11/16/95	3,218,328	Shapiro et al.	1	1	
RB	3.	3/20/79	4,145,435	Szmuszkowicz	1	1	
RB	4.	12/18/79	4,179,501	Szmuszkowicz	1	1	
RB	5.	7/1/86	4,598,087	Horwell	1	1	
RB	6.	4/7/87	4,656,182	Horwell	1	1	
RB	7.	5/5/87	4,663,343	Horwell et al.	1	1	
RB	8.	8/8/89	4,855,316	Horwell et al.	1	1	
RB	9.	11/14/89	4,880,800	Wallis	1	1	
RB	10.	3/6/90	4,906,655	Horwell et al.	1	1	
RB	11.	5/28/91	5,019,588	Horwell et al.	1	1	
RB	12.	9/24/91	5,051,428	Horwell et al.	1	1	
RB	13.	10/22/91	5,059,620	Stout et al.	1	1	
RB	14.	2/20/96	5,492,825	Jan et al.	1	1	
RB	15.	4/9/96	5,506,257	MacLeod et al.	1	1	
RB	16.	6/10/97	5,637,583	MacLeod et al.	1	1	
RB	17.	9/23/97	5,670,335	Jan et al.	1	1	
RB	18.	3/17/98	5,728,535	Lester et al.	1	1	
RB	19.	3/31/98	5,734,021	Lester et al.	1	1	
RB	20.	5/12/98	5,750,537	Nomura et al.	1	1	
RB	21.	10/6/98	5,817,698	Brown et al.	1	1	
RB	22.	3/23/99	5,885,984	MacLeod et al.	1	1	
RB	23.	1/16/01	6,174,879	MacLeod et al.	1	1	
RB	24.	1/30/01	6,180,632	Myers et al.	1	1	

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3/18/05

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FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
Rb	25.	9/30/93	WO 93/19056	PCT	/	/	
Rb	26.	4/14/94	WO 94/07843	PCT	/	/	
Rb	27.	7/7/94	WO 94/14435	PCT	/	/	
Rb	28.	3/30/95	WO 95/08544	PCT	/	/	
Rb	29.	10/26/95	WO 95/28155	PCT	/	/	
Rb	30.	6/20/96	WO 96/18615	PCT	/	/	
Rb	31.	8/8/96	WO 96/23894	PCT	/	/	
Rb	32.	9/12/97	WO 97/32857	PCT	/	/	
Rb	33.	12/31/97	WO 97/49680	PCT	/	/	
Rb	34.	1/21/99	WO 99/02159	PCT	/	/	
Rb	35.	1/28/99	WO 99/03468	PCT	/	/	
Rb	36.	3/11/99	WO 99/11252	PCT	/	/	
Rb	37.	4/8/99	WO 99/16431	PCT	/	/	
Rb	38.	10/7/99	WO 99/50205	PCT	/	/	
Rb	39.	10/7/99	WO 99/50225	PCT	/	/	
Rb	40.	12/24/03	WO 03/105756	PCT	/	/	
Rb	41.	4/5/88	1234808	CA	/	/	
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Rb	46.	3/20/01	2132841	CA	/	/	
Rb	47.	3/30/95	2172513	CA	/	/	
Rb	48.	9/12/97	2240728	CA	/	/	
Rb	49.	1/28/99	2289055	CA	/	/	
Rb	50.	6/6/74	DE 2 259 260	DE	/	/	No
Rb	51.	7/6/78	DE 2 658 401 (English Abstract)	DE	/	/	No

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Robert Anderson

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Rb	52.	12/12/85	DE 3 517 901 (English Abstract)	DE	—	—	No
Rb	53.	5/20/87	0222533 A1	EP	—	—	
Rb	54.	8/1/90	0380063 A1/ B1	EP	—	—	
Rb	55.	7/3/85	0147085 A2/B1	EP	—	—	
Rb	56.	12/19/01	0720605 B1	EP	—	—	
Rb	57.	6/13/90	0372466 A2/A3	EP	—	—	
Rb	58.	7/28/93	0552386 A1	EP	—	—	
Rb	59.	2/28/98	HU 215963 B	HU	—	—	No
Rb	60.	11/5/90	JP 02-270864 (English Abstract)	JP	—	—	No

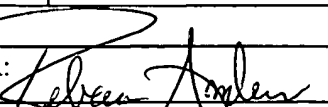
OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
Rb	61.	Adcock, J.J. et al., (2003) "RSD931, a novel anti-tussive agent acting on airway sensory nerves" Br J Pharm, 138:407-416
Rb	62.	Altria, Kevin D. et al., (2001) "Capillary Electrophoresis as a Routine Analytical Tool in Pharmaceutical Analysis" LCGC 19(9): 972-985
Rb	63.	Amin, et al., (1996) "RPR 101821, a New Potent Cholesterol-lowering Agent: Inhibition of Squalene Synthase and 7-Dehydrocholesterol Reductase", Naunyn-Schmiedeberg's Arch Pharmacol 353:233-240
Rb	64.	Bain, et al., (1997) "Better Antiarrhythmics? Development of Antiarrhythmic Drugs Selective for Ischaemia-Dependent Arrhythmias", Drug Development Research 42:198-210
Rb	65.	Barrett, T.D. (2000) "Ischaemia selectivity confers efficacy for suppression of ischaemia-induced arrhythmias in rats" Eur J Pharm, 398:365-374
Rb	66.	Barrett, T. D. et al., (1997) "A model of myocardial ischemia for the simultaneous assessment of electrophysiological changes and arrhythmias in intact rabbits" J Pharmacol Toxicol Methods, 37:27-36
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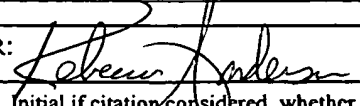
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BPS Proceedings 115P.			
72A	68.	Barrett, T. D. et al., (1996) "Glibenclamide Possesses Transient, Ischaemia Selective Class III Antiarrhythmic Actions But does not Prevent Ischaemic Arrhythmias" BPS Proceedings 116P	
72B	69.	Barrett, Terrance D. (1997) "Ischemia Selective Electrophysiological and antiarrhythmic actions of RSD1019 in ischemic cardiac tissue" J Mol Cell Cardiol, pp 197	
72C	70.	Barrett, Terrance D. et al., (2000) "RSD 1019 suppresses ischaemia-induced monophasic action potential shortening and arrhythmias in anaesthetized rabbits" Br J Pharm, 131:405-414	
72D	71.	Beatch, et al., (2002) "Selectively Prolongs Atrial Refractoriness and Terminates AF in Dogs with Electrically Remodeled Atria", (NASPE) North Amer. Soc. of Pacing & Electrophysiol. 24:698 (Abstract 702)	
72E	72.	Beatch, G. et al., "Effect of a Novel Anti-tussive Compound CP1 Against Citric Acid Induced Cough in Guinea-Pigs" Proc West Pharmacol Soc 20	
72F	73.	Beatch, G. et al., (2003) "Electrophysiological Profile of RSD1235, A New Drug for Conversion of Atrial Fibrillation" Abstracts from AHA Circulation ISSN 0009-7322.	
72G	74.	Beatch, G. et al., "RSD1235 Rapidly and Effectively Terminates Atrial Fibrillation" Abstract submission ESC Congress August 30-September 3, 2003, in Vienna, Austria	
72H	75.	Beatch, G.N. et al., (1996) "Antihistamine-induced Ventricular Arrhythmias" BPS Proceedings 120P	
72I	76.	Beatch, G.N. et al., (1997) "Characterization of a Non-Human Primate Model of Drug-Induced Torsades De Pointes" Proc. West. Pharmacol. Soc., 40: 13-16	
72J	77.	Beatch, G. N. et al., "RSD1235, A Novel Atrial-Selective Antiarrhythmic Drug, Shows Rapid and Extensive Oral Absorption in Man" 12 th International Congress on Cardiovascular Pharmacotherapy, May 7-10, 2003, Barcelona, Spain	
72K	78.	Beatch, G.N. et al., (2002) "RSD1235 Selectively Prolongs Atrial Refractoriness and Terminates AF in Dogs with Electrically Remodeled Atria" PACE 24(Part II):698. Abstract 702	
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Rb	79.	Beatch, G. N. et al., (2002) "Ventricular Fibrillation, and Uncontrolled Arrhythmia Seeking New Targets" Drug Develop Res 55:45-52	
Rb	80.	Bian, et al., (1998) "Effects of K-opioid receptor stimulation in the heart and the involvement of protein kinase C" Brit. J. Pharmacol. 124:600-606	
Rb	81.	Billman, (2003) "RSD-1235", Current Opinion Investigational Drugs 4(3):352-354	
Rb	82.	Boiadjev, et al., (1996) "pH-Sensitive Exciton Chirality Chromophore..Solvatochromic Effects on Circular Dichroism Spectra", Tetrahedron: Asymmetry 7(10):2825-2832	
Rb	83.	Bowen, et al., (1992) "Characterization of the enantiomers of cis-n-[2-(3,4-Dichlorophenyl)Ethyl]-N-Methyl-2-(1-Pyrrolidinyl)Cyclohexylamine (BD737 and BD738): Novel Compounds with High Affinity, Selectivity and Biological Efficacy at Sigma Receptors" J. Pharmacol. Exp. Ther. 262(1):32-40	
Rb	84.	Cardiome Drug Effective for Heart Patients. Press Release, September 3, 2002, 3 pages	
Rb	85.	Cardiome Pharma Corp. Healthcare (Underweight) Company Report December 12, 2002. 26 pages	
Rb	86.	Cardiome Pharma Completes Phase I Safety Study. New Release Transmitted By CNN Newswire, July 30, 2001. 2 pages	
Rb	87.	Cardiome Reports Dosing of First Patient in Pivotal Phase II Study. Press Release January 17, 2002. 3 pages	
Rb	88.	Cardiome Reports Oral Absorption of RSD1235 in Humans. News Release via Canada Newswire (2002). 3 pages	
Rb	89.	Clohs, L. et al., (2002) "Validation of a capillary electrophoresis assay for assessing the metabolic stability of verapamil in human liver microsomes" J Cap Elec & Microchip Tech. 007: 113-117	
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Rb	91.	Clohs, Lilian "Capillary Electrophoresis And Its Applications In The Pharmaceutical Industry" Short Course: One Platform Fits Many Applications. CSC 2002 Short Course, 52 pages	
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RA	92.	Clohs, Lilian "Capillary Electrophoresis as an Analytical Tool in the Drug Discovery Process" Presentation CE Symposium, August, 2000, 40 pages	
RA	93.	Clohs, Lilian et al., (2002) "CE Analysis of Propranolol in Human Serum Using Dynamic Capillary Coating" CE Currents: LCGC Europe, Reader Service 14, pp: 289-293	
RA	94.	Clohs, Lilian. "CE and Drug Metabolism Studies: A Powerful Combination in Drug Discovery" CE Symposium Washington, DC, (August 2002), 31 pages	
RA	95.	Clohs, Lilian (2001) "Pharmacokinetics profiling of new drug candidates: a key process in drug discovery" 4(1): 6	
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RA	97.	Crotti, et al., (1998) "Regiochemical control of the ring-opening of epoxides by means of chelating processes Part 13...", Chemical Abstracts 129(17):662-663, abstract no. 216472k	
RA	98.	Crotti, et al., (1998) "Synthesis and Ring-Opening Reactions of the Diastereoisomeric <i>cis</i> - and <i>trans</i> -Epoxides Derived from 3-(Benzyloxy)cyclopentene and 2-(Benzyloxy)-2,5-dihydrofuran" Eur. J. Org. Chem. 8:1675-1686	
RA	99.	De Costa, Brian R. (1990) "Synthesis and Evaluation of N-Substituted <i>cis</i> -N-Methyl-2-(1-pyrrolidinyl)cyclohexylamines as High Affinity σ Receptor Ligands. Identification of a New Class of Highly Potent and Selective σ Receptor Probes" J Med Chem, 33:3100-3110	
	100.	Doci, A. "Local Anesthetic Effects of Intradermal RSD921 In Healthy Subjects" Clin Pharm & Therapeutics, 65(2): 177	
RA	101.	Duan, D. et al., (1993) "Potassium Channel Blocking Properties of Propafenone in Rabbit Atrial Myocytes" J Pharm Exp Ther 264(3): 1113-1123	
RA	102.	Ezrin, Alan M. et al., (2002) "A Dose-Ranging Study of RSD1235, A Novel Antiarrhythmic Agent, In Healthy Volunteers" Pharmacologist, 44(2) (Supplement I), A15: XIV th World Congress of Pharmacology: Meeting Abstracts	
RA	103.	Ezrin, et al., (2002) "P297 Safety and Pharmacokinetics of RSD1235, a Novel Atrial Fibrillation Converting Drug, in Health Volunteers", Abstracts: 11 th Int. Congress	
EXAMINER: <i>Elaine Anderson</i>		DATE CONSIDERED: 3/18/05	
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Cardiovasc. Pharmacother. 16 Abstract P297			
Re	104.	Ezrin, Alan et al., (2002) "Safety and Pharmacokinetics of RSD1235, A novel Atrial Fibrillation Converting Drug, In Healthy Volunteers & Statins Benefit Coronary Heart Disease Patients more than Hypercholesterolaemic Subjects: Inferences Bases on NNT" Poster Int Soc Cardio Pharm, pp 49	
Re	105.	Fedida, D. et al., (2002) "Kv1.5 is an Important Component of Repolarizing K ⁺ Current in Canine Atrial Myocytes" Circulation Research Peer Review Plus Manuscript PDF, 38 pages	
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	107.	Franciosi, Luigi G. et al., "Phase II Clinical Trial of RSD921 as a Local Anaesthetic in Patients Undergoing Venous Cannulation For Elective Treatment" 28th Annual ACCP Meet Abstract 32, pp 977	
Re	108.	Franciosi, Sonia et al. (2001) "pH-dependent blocking actions of three novel antiarrhythmic compounds on K ⁺ and Na ⁺ currents in rat ventricular myocytes" Eur J Pharm, 425:95-107	
Re	109.	Franciosi L et al. "Development and evaluation of a quality assessment instrument for clinical trial protocols." Pharmacologist 44(2):A160, 2002 (Abstract #98.1, Poster at XIV World Congress of Pharmacology, July 7-12, 2002, San Francisco, CA	
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Re	111.	Friess, et al., (1961) "Central Activity Evoked in the Cat by Cis-Trans Isomers of 1,2-Aminocyclohexanol Derivatives" Toxicol. Appl. Pharmacol. 3:638-653	
Re	112.	Grant, (1998) "Mechanisms of Atrial Fibrillation and Action of Drugs Used in its Management", Am J Cardiol 82:43N-49N	
Re	113.	Halfpenny, Paul R. (1990) "Highly Selective <i>k</i> -Opioid Analgesics. 3. Synthesis and Structure-Activity Relationships of Novel N-[2-(1-Pyrrolidinyl)4- or -5-substituted-cyclohexyl]arylamide Derivatives" J Med Chem, 33:289-291	
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EXAMINER: <i>Sebastian Anderson</i>		DATE CONSIDERED: 3/18/05	
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115.	Hayes, ES. et al., (1997) "Actions of Arylpiperazines on Corpus Cavernosum Smooth Muscle <i>In Vitro</i> " Asia Pac J Pharmacol, 12:97-103		
116.	Hayes, ES. et al., (1997) "Direct Actions of Arylpiperazines on Rabbit and Human Corpus Cavernosum Smooth Muscle <i>In Vitro</i> " Asia Pac J Pharmacol, Abstract S15		
117.	Hayes, E. S. et al., (1996) "RSD992 Enhances Erection and Copulation in Rats and Erection in Primates" Int J Impotence Res, pp 189, (Abstract P24)		
118.	Hesketh, J., et al., "Safety of RSD1235 in a rabbit purkinje fiber model", (XIVth World Congress of Phar.: Meeting Abstracts: 22.12		
119.	Hesketh JC. and Fedida D. et al. "Ionic mechanisms of atrial fibrillation." In <u>Cardiac Drug Development Guide</u> , ed. Pugsley, M. Ch 9, pp163-174, Humana Press, NJ. 2003		
120.	International Search Report mailed on August 3, 1999, for PCT patent application no. PCT/CA99/00280, 5 pages		
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122.	Keefe, D. et al. (1981) "New Antiarrhythmic Drugs: Their Place in Therapy" Drugs 22:363-400		
123.	Kertesz, R. et al., "The Electrophysiological and Antiarrhythmic Actions of RSD Analogs of U50,488H in Rats" Proc west Pharmacol Soc ab. 9 pages		
124.	Lang, C. C. et al., (2000) "Clinical Evaluation of RSD921 As a Local Anaesthetic in Patients Undergoing Venous Cannulation for Elective Treatment" Clin Pharm & Therapeutics, pp 142		
125.	Lewis, et al., (1995) "Enzyme inhibition during the conversion of squalene to cholesterol", Steroids 60:475-483		
126.	Li, G-R. et al., (1996) "Adrenergic Modulation of Ultrarapid Delayed Rectifier K ⁺ current in Human Atrial Myocytes" Circ. Res.78:903-915		
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Chem. 12:965-967			
129.	Matyus, et al., (1997) "Antiarrhythmic Agents: Current Status and Perspective", Medicinal Research Reviews 17(5):427-451		
130.	McLarnon, J. et al., (1996) "Mixed Block of K and Na Currents By KC8851, A Structural of Tedisamil <i>In Vitro</i> and <i>In Vivo</i> Studies" BPS Proceedings 114P		
131.	Moorman, et al., (1986) "pK _a Does Not Predict pH Potentiation of Sodium Channel Blockade by Lidocaine and W6211 in Guinea Pig Ventricular Myocardium ¹ ", The Journal of Pharmacology and Experimental Therapeutics 238(1):159-166		
132.	Morisawa, et al., (1991) "Preparation of fluorocarbocycle nucleosides as antitumor agents", Chemical Abstracts 115(5):904-905, abstract no. 50215n		
133.	Nakahsima, H. et al., (2002) "Angiotensin II Type I Receptor Antagonist Prevents the Promotion of Atrial Fibrillation" PACE 24(Part II):698. Abstract 701		
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136.	Nattel, et al., (2001) "P2362: RSD1235: a novel antiarrhythmic agent with a unique electrophysiological profile that terminates AF in dogs", Eur. Heart J 22(Suppl):448 (Abstract P2362)		
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* no date provided on 1449 or on reference (138) (137)

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	140.	Nortran Arrhythmia Drug Demonstrates Oral Bioavailability. New Release Transmitted By CNN Newswire, June 21, 2001. 2 pages	
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sf- 1807564PTO/SB/ 08 (2-92)

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* no date provided on 1449 or on reference (150)(147)
 * no copy of reference provided, only order form from British Journal of Pharmacology.

Form PTO-1449		Docket Number 554792000401	Application Number 10/674,684
INFORMATION DISCLOSURE CITATION IN AN APPLICATION		Applicant Allan I. Bain et al.	
(Use several sheets if necessary)		Filing Date September 29, 2003	Group Art Unit 1626
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 * no copy of reference provided, only order form from archives of internal medicine (174)

Form PTO-1449	Docket Number 554792000401	Application Number 10/674,684
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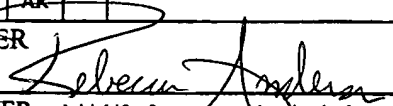
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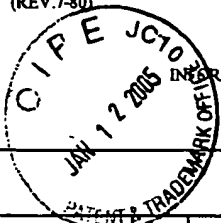

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FORM PTO-1449 (REV. 7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 480102.403C2		APPLICATION NO. 10/674,684	
 <p>INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)</p>				APPLICANTS Allen I. Bain et al.			
				FILING DATE September 29, 2003		GROUP ART UNIT 1626	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
DB	AA 6,210,809	04/03/01	Okutomi et al.	428	546		
BA	AB 6,214,810	04/10/01	Fermini et al.	514	75		
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	DOCUMENT NUMBER	DATE	COUNTRY			TRANSLATION YES NO	
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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)							
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